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Article

Efficacy of Levothyroxine (LT4) and Liothyronine (T3) Combination Therapy vs. LT4 Monotherapy for Hypothyroidism: A Meta-Analysis

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ABSTRACT

Background: Levothyroxine (LT4) monotherapy is the standard treatment for hypothyroidism, using serum thyroid-stimulating hormone (TSH) as the primary indicator of therapeutic adequacy. However, many patients remain symptomatic despite achieving normal TSH levels.

Objectives: This meta-analysis evaluates the biochemical and metabolic efficacy of adding liothyronine (T3) to LT4 compared to standard monotherapy.

Method: A systematic search was conducted to identify randomized controlled trials (RCTs) comparing LT4+T3 combination therapy with LT4 monotherapy in adults. TSH was the primary outcome, while secondary outcomes included free T4 (fT4), total T3, lipid profiles, and body weight.

Results: Seven RCTs involving 355 participants were analyzed. Biochemical outcomes showed no significant difference in TSH suppression (P=0.40) or total T3 levels (P=0.38) between groups. Notably, LT4 monotherapy resulted in significantly higher fT4 levels (MD=0.27; 95%CI: 0.13, 0.40; P=0.0001). Regarding metabolic outcomes, combination therapy significantly improved LDL cholesterol (MD=4.79; 95%CI: 1.63, 7.96; P=0.003) with zero heterogeneity (I2=0%). A borderline significant trend toward weight reduction was also observed in the combination group (MD=-2.26; 95%CI: -4.52, 0.01; P=0.05).

Conclusion: Compared to monotherapy, LT4+T3 combination therapy provides significant metabolic advantages, particularly in LDL reduction, while maintaining biochemical euthyroidism.

Keywords: Hypothyroidism, Levothyroxine, Liothyronine, Meta-analysis

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INTRODUCTION

Primary hypothyroidism is traditionally managed with levothyroxine (LT4) monotherapy, which has long been regarded as the gold standard of treatment (Jonklaas, 2020; Hostalek, 2024). This strategy is based on the assumption that peripheral deiodination of LT4, a prohormone, provides sufficient liothyronine (T3) for tissue needs (Bianco, 2024; Thomas, 2025). Within this model, serum thyroid-stimulating hormone (TSH) serves as the main biochemical marker of euthyroidism and therapeutic adequacy (Peterman, 2025; Shakir et al., 2021). However, despite normalization of TSH, 10–15% of patients continue to experience symptoms such as fatigue, cognitive impairment, and metabolic dissatisfaction (Ettleson, 2022; Suryantini, 2024).

This clinical gap has been described as the “T3 paradox,” where normal TSH levels may not reflect adequate intracellular T3 signaling across all tissues (McAninch, 2018; Bianco, 2024). Evidence indicates that LT4 monotherapy often produces a low serum T3/T4 ratio and elevated free T4 (fT4) levels required to suppress TSH (Uricoechea, 2024). Such a state does not replicate normal thyroid physiology, in which about 20% of circulating T3 is secreted directly by the thyroid and the remaining 80% is generated through peripheral conversion (Azizi et al., 2025; Mehran et al., 2023). Genetic factors, such as the Thr92Ala polymorphism in the type 2 deiodinase (DIO2) gene, may further reduce intracellular T3 availability, supporting the rationale for exogenous T3 supplementation (Premawardhana, 2023; Phan et al., 2025).

The metabolic consequences of insufficient T3 replacement are significant, as T3 regulates basal metabolic rate and lipid metabolism (Kahaly, 2022; Thomas, 2025). Patients treated with LT4 alone often show persistent abnormalities in objective markers such as low-density lipoprotein (LDL) cholesterol and body weight compared with healthy controls (McAninch, 2018; Benabdelkamel, 2022). This suggests that while TSH is a sensitive marker of pituitary-thyroid axis function, it may not reliably indicate metabolic euthyroidism in peripheral tissues such as the liver (Zamwar, 2023; Antonelli, 2021).

Several trials have investigated LT4 plus liothyronine (LT4+T3) combination therapy, with biochemical and metabolic outcomes providing more objective measures than symptom scores (Phan et al., 2025; Hajtalebi et al., 2025). With the recent publication of high-quality randomized controlled trials (RCTs) between 2021 and 2025, there is a timely need to reassess this therapeutic comparison (Ayasa, 2025; Beltrão, 2025). This meta-analysis therefore evaluates LT4+T3 combination therapy versus LT4 monotherapy in adults, focusing on TSH as the primary outcome to ensure comparable thyroid suppression, while also examining metabolic markers such as LDL cholesterol and body weight (Kaminski et al., 2016; Fischman, 2018).

METHODS

Study Design and Guidelines

This study is a systematic review and meta-analysis of randomized controlled trials (RCTs). The protocol followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines to ensure transparency and methodological rigor. The analysis compared the biochemical and metabolic effects of LT4+T3 combination therapy with standard LT4 monotherapy.

Search Strategy and Data Sources

A comprehensive search was conducted in PubMed, Google Scholar, and the Cochrane Library up to 2026. Medical Subject Headings (MeSH) and keywords such as hypothyroidism, levothyroxine, liothyronine, and metabolic outcomes were used. Reference lists of included studies were also screened to identify additional relevant publications.

Eligibility Criteria

Study selection was guided by the PICO framework. Eligible participants were adults (≥18 years) diagnosed with primary hypothyroidism, including those who had undergone thyroidectomy or radioiodine therapy for benign conditions. The

intervention of interest was LT4+T3 combination therapy, regardless of dosage ratio or formulation type. The comparator was standard LT4 monotherapy aimed at achieving biochemical and clinical euthyroidism. Only RCTs with parallel or crossover designs were included. Studies were required to report serum thyroid-stimulating hormone (TSH) as the primary biochemical outcome to ensure comparability across treatment arms. Secondary outcomes included free thyroxine (fT4), total liothyronine (T3), low-density lipoprotein (LDL) cholesterol, total cholesterol, and body weight. Exclusion criteria were studies involving pediatric populations, pregnant women, patients with central hypothyroidism, or those using desiccated thyroid extracts.

Study Selection and Data Extraction

Following the PRISMA flow diagram, 180 records were identified. After removing duplicates and screening abstracts, 21 full-text articles were assessed. Seven RCTs involving 355 participants met the inclusion criteria and were included in the quantitative synthesis. Data extraction included study characteristics (author, country, design) and quantitative results for biochemical and metabolic parameters.

Quality Assessment and Risk of Bias

The methodological quality of the included studies was assessed using the Cochrane Risk of Bias 2 (RoB 2) tool, which evaluates five domains: randomization process, deviations from intended interventions, missing outcome data, measurement of outcomes, and selection of reported results. Each domain was judged as low risk, some concerns, or high risk, and overall study quality was determined based on these ratings. Two independent reviewers conducted the assessment, and any disagreements were resolved through discussion or consultation with a third reviewer to ensure consistency.

Data Analysis

Statistical analyses were performed using Review Manager (RevMan) version 5.4. Heterogeneity was assessed with the Chi-square test and the I^2 statistic. A random-effects model was applied when heterogeneity was high ($I^2 > 50\%$), while a fixed-effects model was used when heterogeneity was low. Effect sizes were expressed as mean differences (MD) with 95% confidence intervals (CI). For biochemical outcomes, TSH was prioritized as the primary endpoint to ensure comparable thyroid suppression across treatment groups. Secondary analyses focused on metabolic markers, including LDL cholesterol, total cholesterol, and body weight. Sensitivity analyses were conducted by excluding studies with high risk of bias, and publication bias was evaluated using funnel plots when ≥10 studies were available.

RESULTS

Study Selection and Characteristics

The systematic search identified a total of 180 records across the electronic databases. Following the removal of 55 duplicates and preliminary screening of titles and abstracts, 21 reports were retrieved for full-text evaluation. Ultimately, seven randomized controlled trials met the eligibility criteria and were included in the meta-analysis (Azizi et al., 2025; Brigante et al., 2024; Hajtalebi et al., 2025; Kaminski et al., 2016; Mehran et al., 2023; Phan et al., 2025; Shakir et al., 2021).

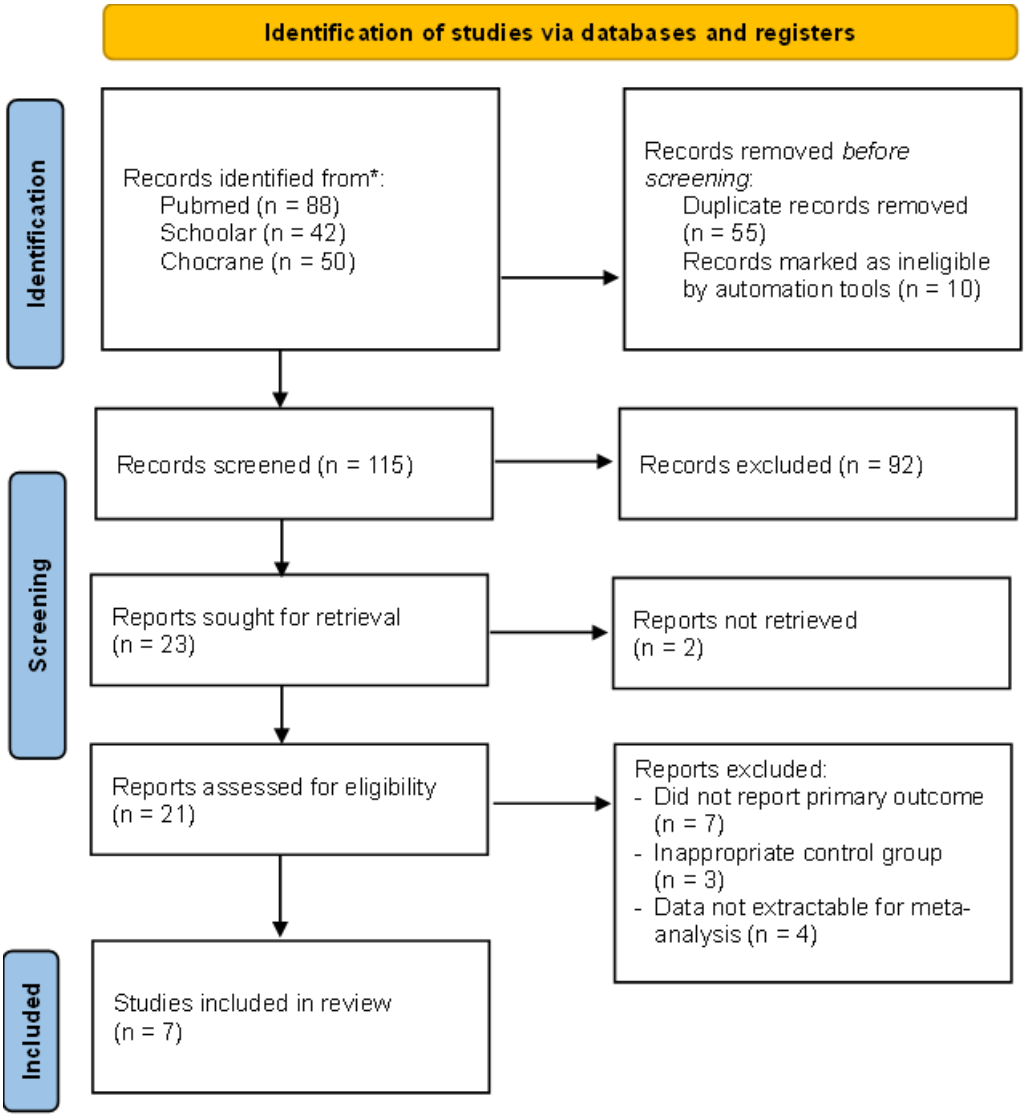

Figure 1. PRISMA 2020 Flow Diagram

These studies involved a total of 355 unique participants, utilizing both parallel and crossover designs. The included trials were conducted across diverse geographical regions including Iran, Italy, the United States, and Brazil, with treatment durations ranging from six weeks to one year. The primary focus of these trials was the comparison between standard levothyroxine monotherapy and various ratios of levothyroxine plus liothyronine combination therapy.

Quality Assessment

The methodological quality was assessed using the Cochrane Risk of Bias 2 tool, which revealed a generally robust level of evidence across the included trials. Most studies demonstrated a low risk of bias or only minor concerns. The trials by Shakir et al. (2021) and Hajtalebi et al. (2025) were identified as having a low risk of bias across all five domains. Some concerns were noted in the randomization

process or deviations from intended interventions in the earlier trials by Kaminski et al. (2016) and smaller pilot studies such as Mehran et al. (2023). However, no study was excluded based on high risk of bias, ensuring a comprehensive synthesis of the available biochemical and metabolic data.

Table 1. Characteristics of Included Studies

Author & Year	Country	Study Design	Setting	Total Sample (LT4 vs T4+T3)	Participant Characteristics
Azizi et al., 2025	Iran	Parallel RCT	Endocrine Research Center	n=32 (16 vs 16)	Women (47 ± 11 yrs), primary hypothyroidism
Brigante et al., 2024	Italy	Crossover RCT	University Hospital	n=34 (34 vs 34)	Adults (49 ± 11.2 yrs), post-total thyroidectomy
Phan et al., 2025	USA	Double-blind trial	Academic medical center	n=12 (7 vs 5)	Adults (51.7 ± 13.8 yrs), post-total thyroidectomy
Shakir et al., 2021	USA	Crossover RCT	Military health clinics	n=75 (75 vs 75)	Adults (mean 50), majority Hashimoto's
Kaminski et al., 2016	Brazil	Crossover RCT	University Hospital	n=32 (32 vs 32)	Adults (42.6 ± 13.3 yrs), 94% female
Hajtalebi et al., 2025	Iran	Parallel RCT	Academic medical center	n=151 (80 vs 71)	Adults (mean 42-43), symptomatic despite normal TSH
Mehran et al., 2023	Iran	Parallel RCT	Endocrine Clinic	n=19 (10 vs 9)	Adults (59.1 ± 7.8 yrs), post-radioiodine

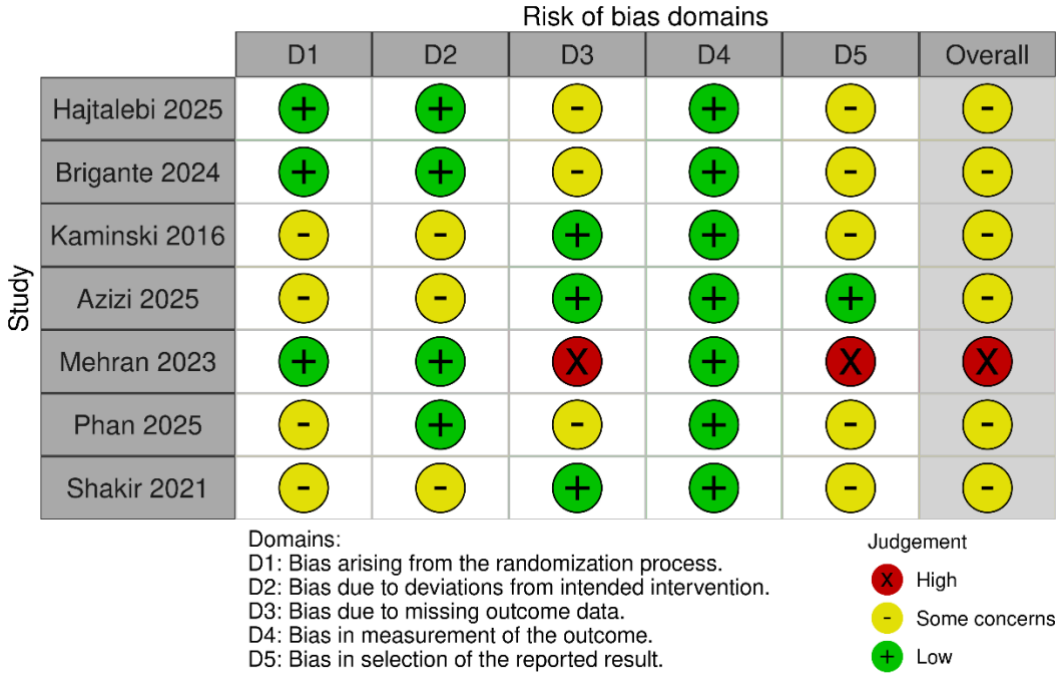

Figure 2. Cochrane Risk of Bias 2 tool

Biochemical Outcomes

Serum Thyroid-Stimulating Hormone (TSH)

As the primary outcome of this meta-analysis, TSH levels were reported across all seven studies involving 496 observations. The pooled analysis using a random-effects model showed no significant difference between the LT4+T3 combination therapy and LT4 monotherapy groups (MD = -0.14; 95% CI: -0.47, 0.19; P = 0.40). This indicates that both therapeutic approaches achieved comparable levels of pituitary-thyroid axis suppression. High heterogeneity was observed for this parameter (I2 = 77%), likely reflecting variations in dosage adjustments and baseline TSH levels across the different study protocols.

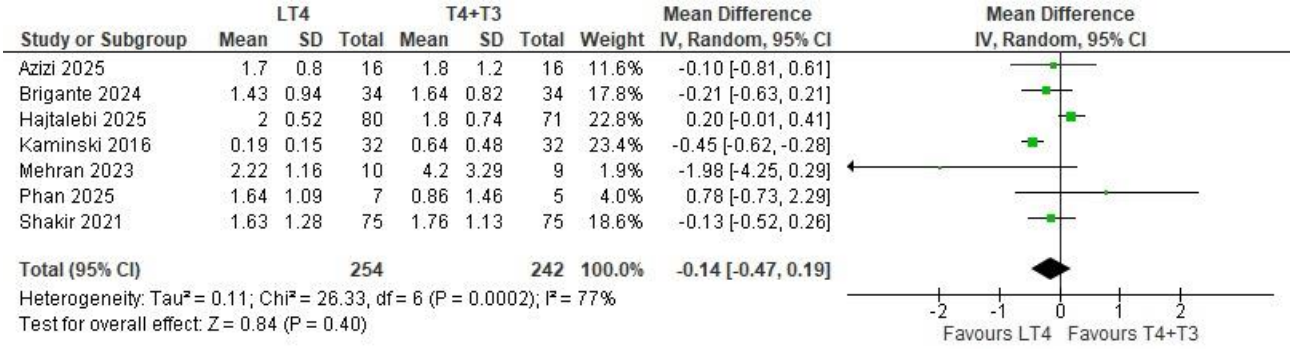

Figure 3. Forrest Plot Serum Thyroid-Stimulating Hormone (TSH)

Free Thyroxine (fT4)

The analysis of fT4 levels across six trials demonstrated a significant difference favoring the LT4 monotherapy group. Participants receiving monotherapy exhibited significantly higher fT4 levels compared to those on combination therapy (MD = 0.27; 95% CI: 0.13, 0.40; P = 0.0001). This finding is consistent with the physiological expectation that the absence of exogenous T3 requires higher LT4 doses to normalize peripheral T3 levels through deiodination. Heterogeneity for this outcome was substantial at I^2 = 78%.

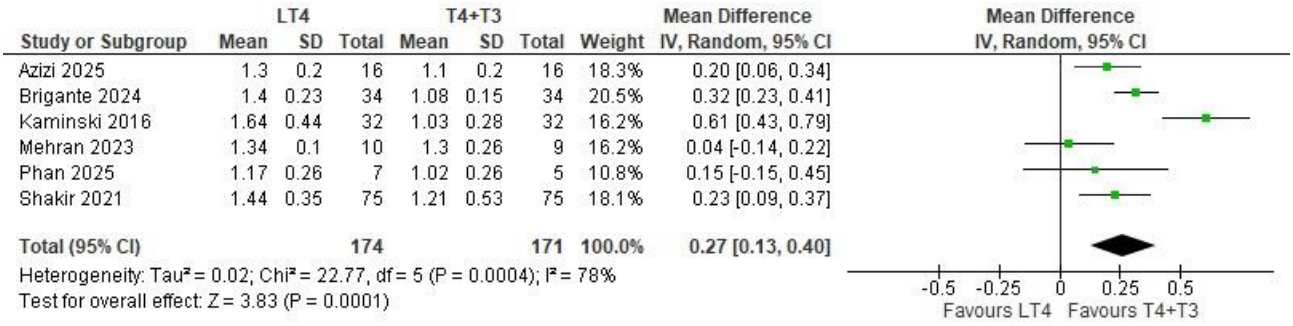

Figure 4. Forrest Plot Free Thyroxine (fT4)

Total Liothyronine (T3)

Data from five trials showed that total T3 levels remained comparable between the two groups with no statistically significant difference (MD = -8.75; 95% CI: -28.39, 10.89; P = 0.38). Despite the direct administration of T3 in the intervention group, the pooled results using a random-effects model exhibited high heterogeneity (I^2 = 91%), possibly due to the timing of blood sampling relative to T3 dosing.

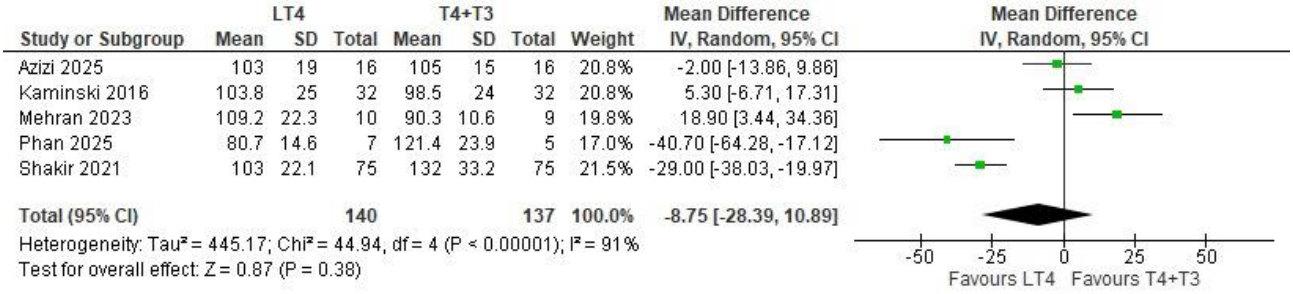

Figure 5. Forrest Plot Total Liothyronine (T3)

Metabolic Outcomes

Total Cholesterol

In contrast to the LDL findings, total cholesterol levels did not show a significant difference between the two groups across five trials (MD = 1.17; 95% CI: -7.06, 9.40; P = 0.78). The data demonstrated excellent consistency with no observed heterogeneity (I^2 = 0%).

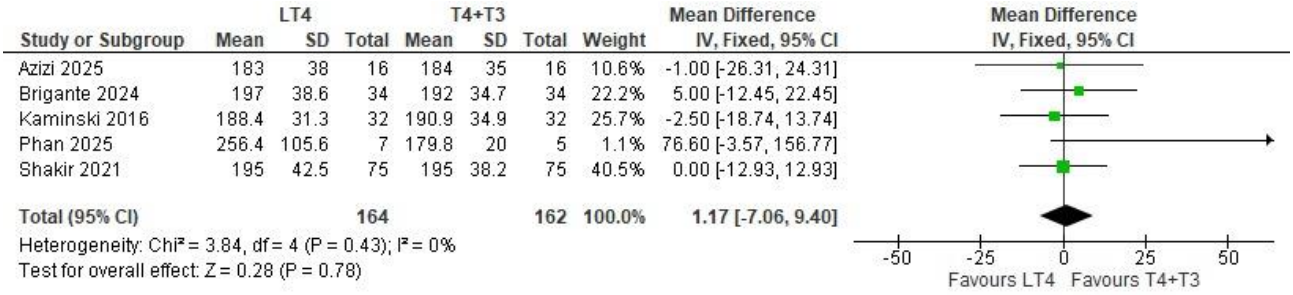

Figure 6. Forrest Plot Total Cholesterol

Low-Density Lipoprotein (LDL)

The most significant metabolic finding was the reduction of LDL cholesterol levels. Analysis of five studies using a fixed-effects model showed that LT4+T3 combination therapy resulted in significantly lower LDL levels compared to monotherapy (MD = 4.79; 95% CI: 1.63, 7.96; P = 0.003). Notably, there was zero heterogeneity observed for this outcome (I^2 = 0%), suggesting highly consistent results across the included trials regarding the lipid-lowering potential of T3.

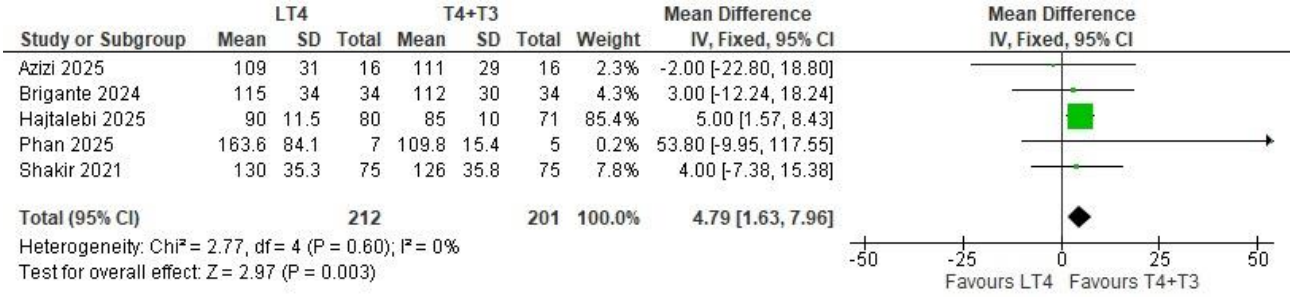

Figure 7. Forrest Plot Low-Density Lipoprotein (LDL)

Body Weight

The impact on body weight was assessed across seven trials. The results demonstrated a borderline significant trend toward weight reduction in the combination therapy group (MD = -2.26; 95% CI: -4.52, 0.01; P = 0.05). Similar to the LDL findings, the heterogeneity for weight was non-existent (I^2 = 0%), reinforcing the consistency of this metabolic trend.

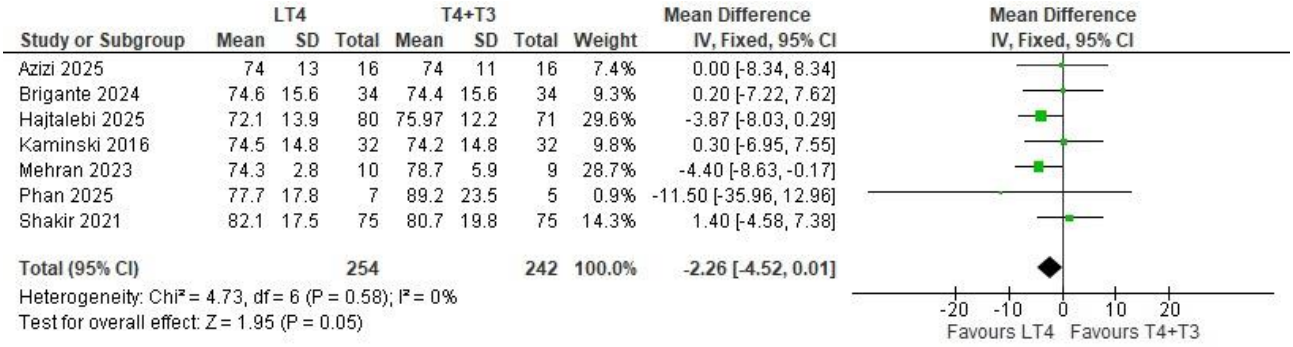

Figure 8. Forrest Plot Body Weight

DISCUSSION

The primary goal of thyroid hormone replacement therapy is to achieve biochemical euthyroidism, most commonly defined by normalization of serum thyroid-stimulating hormone (TSH) (Wilson, Stem, & Bruehlman, 2021). Our meta-analysis confirms that both LT4 monotherapy and LT4+T3 combination therapy are equally effective in suppressing TSH, with no significant difference between groups (P=0.40). This finding is consistent with previous reports by Azizi et al. (2025) and Brigante et al. (2024), which demonstrated that TSH levels remained within the reference range regardless of treatment modality.

Despite this similarity, important biochemical distinctions were observed in free thyroxine (fT4) levels. LT4 monotherapy was associated with significantly higher fT4 compared to combination therapy (MD=0.27; P=0.0001). Elevated fT4 in monotherapy is often interpreted as a compensatory mechanism to drive peripheral conversion into T3 in the absence of exogenous supplementation (McAninch et al., 2018). In contrast, the lower fT4 levels observed in combination therapy, as reported by Shakir et al. (2021) and Kaminski et al. (2016), suggest a more physiological balance that better reflects natural thyroid hormone secretion. This pattern may

reduce the risk of localized tissue thyrotoxicosis and provide a hormonal milieu closer to normal physiology (Bianco, 2024).

One of the most clinically relevant findings of this review is the superior metabolic profile associated with combination therapy, particularly in relation to low-density lipoprotein (LDL) cholesterol. Our pooled analysis demonstrated a significant reduction in LDL levels (MD=4.79; P=0.003) with no heterogeneity (I^2=0%). This robust result supports the hypothesis that T3 exerts a more direct regulatory effect on hepatic LDL receptor expression compared to T4 (Benabdelkamel et al., 2022). Although total cholesterol and TSH did not differ substantially between groups, the specific improvement in LDL cholesterol highlights the potential cardiovascular benefits of combination therapy. These findings align with Hajtalebi et al. (2025), who noted that metabolic parameters often favored LT3 inclusion even when quality-of-life scores were comparable. Persistent dyslipidemia in patients treated with LT4 alone remains a common challenge, underscoring the clinical importance of this metabolic advantage (Ettleson & Papaleontiou, 2022).

Our analysis also identified a borderline significant trend toward weight reduction in the combination group (MD = -2.26; P=0.05). While individual studies such as Mehran et al. (2023) and Phan et al. (2025) reported minimal changes in body weight, the pooled data suggest that exogenous T3 may enhance resting energy expenditure. Mechanistically, this effect is likely mediated through activation of brown adipose tissue and mitochondrial thermogenesis, processes that are more sensitive to T3 than T4 (Vargas-Uricoechea & Wartofsky, 2024). Even modest weight reduction, when combined with improved lipid profiles, positions LT4+T3 therapy as a potentially valuable option for patients with metabolic syndrome or persistent weight gain despite normalized TSH (Hostalek & Tayrouz, 2024).

Our findings both confirm and extend previous systematic reviews. Similar to Ayasa et al. (2025), we observed that biochemical euthyroidism is maintained across both therapies. However, unlike earlier reviews that emphasized subjective quality-of-life outcomes (Fischman & Dominguez, 2018), our study highlights objective metabolic markers—specifically LDL cholesterol and body weight—where combination therapy demonstrates measurable benefits.

Interestingly, our analysis found no significant difference in serum T3 levels between groups (P=0.38). This contrasts with older trials but aligns with more recent studies employing slow-release T3 formulations (Azizi et al., 2025; Mehran et al., 2023). These findings suggest that the mode of T3 delivery is critical for maintaining stable serum concentrations and avoiding fluctuations that previously raised safety concerns (Jonklaas et al., 2021).

Despite these promising results, several limitations must be acknowledged. The total sample size across the seven included RCTs was relatively small (n=355), which may limit the generalizability of findings. Additionally, genetic polymorphisms such as the DIO2 Thr92Ala variant, known to influence individual responsiveness to T3, were not consistently reported across studies (Premawardhana et al., 2023; Beltrão et al., 2025). Future research should therefore prioritize large-scale, multicenter RCTs that stratify participants by genetic background and incorporate sustained-release T3 formulations. Such studies would provide stronger evidence to clarify the metabolic and cardiovascular benefits of combination therapy and help

identify patient subgroups most likely to benefit (Thomas, 2025; Zamwar & Muneshwar, 2023).

CONCLUSION

Combination of levothyroxine and liothyronine therapy offers superior metabolic advantages over levothyroxine monotherapy by significantly reducing LDL cholesterol levels and demonstrating a borderline trend toward body weight reduction. While both therapeutic strategies maintain comparable thyroid-stimulating hormone suppression, the biochemical profile of the combination group exhibits lower free thyroxine levels, which potentially reflects a more physiological hormonal state compared to the supra-physiological levels often required in monotherapy. These findings suggest that this combined approach represents a beneficial alternative for hypothyroid patients experiencing persistent metabolic dysfunction, although large-scale trials incorporating genetic screening remain necessary to further optimize personalized treatment strategies.

CONFLICT OF INTEREST

The authors stated there is no conflict of interest in this study.

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